General

Guideline Title

Patient blood management guidelines: module 1 - critical bleeding/massive transfusion.

Bibliographic Source(s)

National Blood Authority. Patient blood management guidelines: module 1 - critical bleeding/massive transfusion. Canberra ACT (Australia): National Blood Authority; 2011. 104 p. [100 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the levels of evidence (I, II, III-1, III-2, III-3, IV) and grades of recommendations (A-D, Practice Point) are provided at the end of the "Major Recommendations" field.

Recommendations

It is recommended that institutions develop a massive transfusion protocol (MTP) that includes the dose, timing and ratio of blood component therapy for use in trauma patients with, or at risk of, critical bleeding requiring massive transfusion (Grade C) (Cotton et al., 2009; Dente et al., 2009).

The routine use of recombinant activated factor VII (rFVIIa) in trauma patients with critical bleeding requiring massive transfusion is not recommended because of its lack of effect on mortality (Grade B) (Boffard et al., 2005) and variable effect on morbidity (Grade C) (Boffard et al., 2005).

Practice Points

In patients with critical bleeding requiring massive transfusion, the following parameters should be measured early and frequently:

- Temperature
- Acid–base status
- Ionised calcium
- Haemoglobin

- Platelet count
- Prothrombin time (PT)/international normalised ratio (INR)
- Activated partial thromboplastin time (APTT)
- Fibrinogen level

With successful treatment, values should trend towards normal.

Values indicative of critical physiologic derangement include:

- Temperature <35°C
- pH <7.2, base excess >–6, lactate >4 mmol/L
- Ionised calcium <1.1 mmol/L
- Platelet count $<50 \times 10^9$/L
- PT >1.5 × normal
- INR >1.5
- APTT >1.5 × normal
- Fibrinogen level <1.0 g/L

In critically bleeding patients requiring, or anticipated to require, massive transfusion, an MTP[a] should be used. A template MTP is provided in the original guideline document.[b]

In patients with critical bleeding requiring massive transfusion, insufficient evidence was identified to support or refute the use of *specific* ratios of red blood cells (RBCs) to blood components.

In patients with critical bleeding requiring massive transfusion, haemoglobin concentration should be interpreted in the context of haemodynamic status, organ perfusion and tissue oxygenation.

In patients with critical bleeding requiring massive transfusion, the use of RBC and other blood components may be life saving. However, transfusion of increased volumes of RBC and other blood components may be independently associated with increased mortality and acute respiratory distress syndrome (ARDS).

In patients with critical bleeding requiring massive transfusion, the use of an MTP to facilitate timely and appropriate use of RBC and other blood components may reduce the risk of mortality and ARDS.

An MTP should include advice on the administration of rFVIIa when conventional measures – including surgical haemostasis and component therapy – have failed to control critical bleeding. Note: rFVIIa is not licensed for this use. Its use should only be considered in exceptional circumstances where survival is considered a credible outcome (see Template MTP example in the original guideline document).

When rFVIIa is administered to patients with critical bleeding requiring massive transfusion, an initial dose of 90 µg/kg is reasonable.

In patients with critical bleeding requiring massive transfusion, suggested doses of blood components are:[c]

- Fresh frozen plasma (FFP): 15 mL/kg
- Platelets: 1 adult therapeutic dose
- Cryoprecipitate: 3–4 g

[a]The use of the word 'protocol' in 'massive transfusion protocol' throughout this report is not strictly prescriptive.

[b]The template MTP is intended for local adaptation.

[c]Or as directed by the haematologist/transfusion specialist in specific clinical situations, such as obstetrics.

Definitions

National Health and Medical Research Council (NHMRC) Evidence Hierarchy: Designations of Levels of Evidence According to Type of Research Question*

Level	Intervention[a]	Prognosis	Aetiology[b]

Level[c]	Intervention[a]	Prognosis	Aetiology[b]
I	A systematic review of Level II studies	A systematic review of Level II studies	A systematic review of Level II studies
II	A randomised controlled trial	A prospective cohort study[d]	A prospective cohort study
III-1	A pseudo randomised controlled trial (i.e., alternate allocation or some other method)	All or none[e]	All or none[e]
III-2	A comparative study with concurrent controls: • Non-randomised, experimental trial[f] • Cohort study • Case–control study • Interrupted time series with a control group	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study
III-3	A comparative study without concurrent controls: • Historical control study • Two or more single arm study[g] • Interrupted time series without a parallel control group	A retrospective cohort study	A case–control study
IV	Case series with either post-test or pre-test/post-test outcomes	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series

*Source: National Health and Medical Research Council (NHMRC) (2009). NHMRC additional levels of evidence and grades for recommendations for developers of guidelines. NHMRC. https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/developers/nhmrc_levels_grades_evidence_120423.pdf

[a]Definitions of these study designs are provided on pages 7-8, *How to use the evidence: assessment and application of scientific evidence* (NHMRC, 2000).

[b]If it is possible and ethical to determine a causal relationship using experimental evidence, then the 'intervention' hierarchy of evidence should be utilised. If it is only possible or ethical to determine a causal relationship using observational evidence (e.g., groups cannot be allocated to a potential harmful exposure, such as nuclear radiation), then the 'aetiology' hierarchy of evidence should be utilised.

[c]A systematic review will only be assigned a level of evidence as high as the studies it contains, except where those studies contain Level II evidence. Systematic reviews of Level II evidence provide more data than the individual studies, and any meta-analyses will increase the precision of the overall results, reducing the likelihood that the results are affected by chance. Systematic reviews of lower level evidence present results of likely poor internal validity and thus are rated on the likelihood that the results have been affected by bias, rather than whether the systematic review itself is of good quality. Systematic review quality should be assessed separately. A systematic review should consist of at least two studies. In systematic reviews that include different study designs, the overall level of evidence should relate to each individual outcome or result, as different studies (and study designs) might contribute to each different outcome.

[d]At study inception, the cohort is either non-diseased or all at the same stage of the disease. A randomised controlled trial with persons either non-diseased or at the same stage of the disease in both arms of the trial would also meet the criterion for this level of evidence.

[e]All or none of the people with the risk factor(s) experience the outcome; and the data arises from an unselected or representative case series which provides an unbiased representation of the prognostic effect. For example, no smallpox develops in the absence of the specific virus; and clear proof of the causal link has come from the disappearance of smallpox after large-scale vaccination.

[f]This also includes controlled before-and-after (pre-test/post-test) studies, as well as indirect comparisons (i.e., utilise A vs. B and B vs. C to determine A vs. C).

[g]Comparing single arm studies, i.e., case series from two studies. This would also include unadjusted indirect comparisons (i.e., utilise A vs. B and B vs. C to determine A vs. C, without statistical adjustment for B).

Body of Evidence Matrix

Component	A	B	C	D
	Excellent	Good	Satisfactory	Poor
Evidence Base	Several Level I or II studies with low risk of bias	One or two Level II studies with low risk of bias or a systematic review, or multiple Level III studies with low risk of bias	Level III studies with low risk of bias, or Level I or II studies with moderate risk of bias	Level IV studies, or Level I to III studies with high risk of bias
Consistency	All studies consistent	Most studies consistent and inconsistency can be explained	Some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical Impact	Very large	Substantial	Moderate	Slight or restricted
Generalisability	Population/s studied in body of evidence are the same as the target population for the guideline	Population/s studied in the body of evidence are similar to the target population for the guideline	Population/s studied in the body of evidence are different to the target population but it is clinically sensible to apply this evidence to the target population for the guidelines	Population/s studied in the body of evidence are different to the target population, and it is hard to judge whether it is sensible to generalise to the target population for the guidelines
Applicability	Directly applicable to the Australian healthcare context	Applicable to Australian healthcare context, with a few caveats	Probably applicable to Australian healthcare context with some caveats	Not applicable to the Australian healthcare context

Grade of Recommendation

Grade A: Body of evidence can be trusted to guide practice.

Grade B: Body of evidence can be trusted to guide practice in most situations.

Grade C: Body of evidence provides some support for recommendation(s) but care should be taken in its application.

Grade D: Body of evidence is weak and recommendations must be applied with caution.

Practice Point: The systematic review found insufficient high-quality data to produce evidence-based recommendations, but the Clinical/Consumer Reference Group (CRG) felt that clinicians require guidance to ensure good clinical practice.

Clinical Algorithm(s)

An algorithm titled "Massive Transfusion Protocol Template" is provided in the original guideline document.

Scope

Disease/Condition(s)

Critical bleeding requiring massive blood transfusion

Guideline Category

Evaluation

Management

Prevention

Treatment

Clinical Specialty

Critical Care

Emergency Medicine

Hematology

Surgery

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To assist and guide health-care professionals in making clinical decisions when managing patients with critical bleeding who require, or are likely to require, massive transfusion

Target Population

Children and adults with critical bleeding who require, or are likely to require, massive transfusion

Interventions and Practices Considered

1. Development of a massive transfusion protocol (MTP) including the dose, timing, and ratio of blood component therapy for use in trauma patients
2. Use of recombinant activated factor VII (rFVIIa)
3. Measurement of clinical and laboratory parameters and assessment for critical physiologic derangement: temperature, acid-base status, ionised calcium, haemoglobin, platelet count, prothrombin time/international normalised ratio (PT/INR), activated partial thromboplastin time (APTT), fibrinogen level
4. Use of red blood cell and other blood components
5. Use of fresh frozen plasma (FFP), platelets, and cryoprecipitates

Major Outcomes Considered

- Morbidity
- Mortality
- Transfusion frequency and dosage/type of transfusion
- Quality of life
- Change in haemoglobin (pre-operative, post-operative, discharge and 28-day haemoglobin levels)
- Cost
- Hospital length of stay (LOS)
- Intensive care unit admission and LOS
- Hospital readmission
- Reoperation for bleeding
- Correction/prevention of disseminated intravascular coagulation (DIC) and coagulopathy

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The clinical research questions for systematic review were structured according to PICO ('population, intervention, comparator and outcome' for intervention questions), PPO ('population, predictor and outcome' for prognostic questions) or PRO ('population, risk factor and outcome' for aetiology questions) criteria. Three main strategies were used to identify potentially relevant literature: electronic database searching, manual searching and use of literature recommended by expert members of the Clinical/Consumer Reference Group (CRG). The primary databases searched were EMBASE, Medline, the Cochrane Library Database and PreMedline. Additional searches were conducted of Cumulative Index to Nursing and Allied Health Literature and Australasian Medical Index. The electronic searches included articles published between 1966 and April–June 2009.

Inclusion criteria were determined from the PICO, PPO or PRO criteria that formed the basis of the systematically reviewed research questions. Non-English publications were excluded.

See Technical Report Volumes 1 and 2 for further details on search strategies and inclusion criteria (see the "Availability of Companion Documents" field).

Number of Source Documents

See Appendix C in Technical Report Volume 2 (see the "Availability of Companion Documents" field) for diagrams depicting literature search results and included studies for all review questions.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

National Health and Medical Research Council (NHMRC) Evidence Hierarchy: Designations of Levels of Evidence According to Type of

Research Question*

Level	Intervention[a]	Prognosis	Aetiology[b]
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[d]At study inception, the cohort is either non-diseased or all at the same stage of the disease. A randomised controlled trial with persons either non-diseased or at the same stage of the disease in both arms of the trial would also meet the criterion for this level of evidence.

[e]All or none of the people with the risk factor(s) experience the outcome; and the data arises from an unselected or representative case series which provides an unbiased representation of the prognostic effect. For example, no smallpox develops in the absence of the specific virus; and clear proof of the causal link has come from the disappearance of smallpox after large-scale vaccination.

[f]This also includes controlled before-and-after (pre-test/post-test) studies, as well as indirect comparisons (i.e., utilise A vs. B and B vs. C to determine A vs. C).

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Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Systematic reviews were undertaken to attempt to answer the questions specific to critical bleeding or massive transfusion, and the generic questions relevant to all six modules. The systematic review questions are listed in Box 2.1 in the original guideline document. Refer to the Technical Reports (see the "Availability of Companion Documents" field) for details concerning the systematic review process and all evidence summary tables.

Classification and Assessment of Evidence

Studies identified from the literature search for inclusion were classified according to the National Health and Medical Research Council (NHMRC) levels of evidence hierarchy (see the "Rating Scheme for the Strength of the Evidence" field). To ensure that guidelines were based on the best available evidence, studies of higher levels of evidence (i.e., Level I or II) were included in preference to those presenting lower levels (III or IV) of evidence. This was done to minimise the potential for bias in the evidence base for each systematically reviewed question. However,

lower level studies were reviewed where evidence was not available in higher level studies for any of the primary outcomes.

Studies identified from the systematic literature review were assessed according to the NHMRC dimensions of evidence (see Table 2.2 in Technical Report Volume 1). There are three main domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain was derived directly from the literature identified for a particular intervention, aetiology or prognostic study. The other two domains were determined in consultation with the Clinical/Consumer Reference Group (CRG) as part of the study assessment process during the review of the evidence considered for guideline development. One aspect of the strength of the evidence domain is the level of evidence of the study, which was determined using the NHMRC levels of evidence outlined in the "Rating Scheme for the Strength of the Evidence" field.

Quality Appraisal

The methodological quality of the included studies was assessed using the criteria presented in Appendix 2 of Technical Report Volume 1. Quality assessment criteria varied according to whether included studies were systematic reviews, randomised controlled trials or cohort studies. No weighting of quality criteria was applied, but studies that met all criteria, or all but one, were considered to be of good quality with a low risk of bias. Because all included studies for question 1 were case reports, it was not possible to appraise the quality of studies included. Quality assessments of included studies for all systematically reviewed questions are presented in Appendix E of Technical Report Volume 2.

Data Extraction

Data and information, according to the inclusion criteria (population, intervention, comparator, outcome [PICO], population, risk, outcome [PRO] or population, predictor, outcome [PPO]), were extracted into evidence summary tables, which were based on NHMRC requirements for externally developed guidelines. Extracted data and information included general study details (citation, study design, evidence level, country and setting), characteristics of study participants, details of interventions and comparators, details pertaining to internal (e.g., allocation and blinding) and external (applicability and generalisibility) study validity, and results for outcomes specified in the inclusion criteria. Where relevant studies were identified, extracted data and information were used to construct study characteristics and results tables of included evidence for each systematically reviewed question. Evidence summary tables for all included studies are presented in Appendix F in Technical Report Volume 2.

Assessment of the Body of Evidence

The body of evidence for each guideline recommendation was graded in accordance with the NHMRC framework for developing evidence-based recommendations. The body of evidence considers the dimensions of evidence of studies relevant to that recommendation. The NHMRC developed an evidence statement form to be used with each clinical research question considered in guidelines development (see Appendix 3 of Technical Report Volume 1). Before completing the evidence statement form, included studies were critically appraised and relevant data were summarised, as described. This information was required to formulate each recommendation and determine the overall grade of the body of evidence supporting each recommendation.

The key findings from included studies were summarised as evidence statements for each systematically reviewed research question. Where required, separate evidence statements were developed for different patient populations or outcomes. Input from the CRG helped to ensure that the size of effects and relevance of evidence were considered when developing evidence statements. Where no evidence or insufficient relevant evidence was identified, this was explained in the evidence statement.

Refer to Technical Report Volume 1 for Steps 1 and 2 in using the NHMRC evidence statement form. Completed evidence statement forms for each research question are presented in Appendix D of Technical Report Volume 2.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The Clinical/Consumer Reference Group (CRG) developed recommendations where sufficient evidence was available from the systematic review of the literature. The recommendations have been carefully worded to reflect the strength of the body of evidence. Each recommendation has been given a grade, which were set by the National Health and Medical Research Council (NHMRC) (see section 2 in the original guideline document for further information on this process).

Governance Structure

A multilevel management framework was established by the National Blood Authority (NBA) to coordinate the development of the new patient blood management guidelines. The management framework (illustrated in Appendix A of the original guideline document) consists of:

- A Steering Committee, responsible for the overall development and governance of the entire project
- An Expert Working Group (EWG), responsible for clinical oversight and integration of the six modules
- Clinical/Consumer Reference Groups (CRGs – one for each of the six modules), with membership including representation from relevant colleges, societies and consumer groups, to provide expert knowledge and input
- Systematic reviewers and a technical writer, contracted by the NBA to review the literature and develop a draft of each module
- Guidelines Assessment Register (GAR) consultants, to provide advice and mentoring to the systematic reviewers, technical writer, EWG and CRGs; and to ensure that the development process and the guidelines produced comply with National Health and Medical Research Council (NHMRC) requirements.

The NBA provided the secretariat, project funding and project management. The NBA Web site includes a list of colleges and societies that have endorsed these guidelines. Appendix A of the original guideline document lists the membership of the bodies involved in governance of the guidelines. Details of how the guidelines will be implemented and updated are provided in Chapter 6 of the guideline.

Formulation of Recommendations

Use of the NHMRC Evidence Statement Form

Step 3: Formulation of a Recommendation Based on the Body of Evidence

Step 3 involved formulating the wording of the recommendation. The wording was intended to reflect the strength of the body evidence; that is, where the evidence base was regarded as poor or unreliable, words such as 'must' or 'should' were not used. The wording of recommendations was developed in conjunction with the CRG during meetings to review the evidence base for research questions.

Step 4: Determination of the Grade for the Recommendation

The overall grade for each recommendation was determined from a summary of the rating for each component of the body of evidence (outlined in the "Rating Scheme for the Strength of the Evidence" field). For transparency, grading was conducted for the evidence statement(s) that were intended to underpin each recommendation. Hence, the overall grades of the recommendations indicate the strength of the body of evidence for the evidence statement(s) underpinning the recommendations. Definitions of the NHMRC grades of recommendations are presented in the "Rating Scheme for the Strength of the Recommendations" field. In accordance with the NHMRC framework, recommendations were not graded A or B unless the evidence base and consistency of evidence were both rated A or B. The grading of recommendations was determined in conjunction with the CRG.

Developed recommendations were entered into the NHMRC evidence statement forms to accompany the corresponding evidence statement matrix, along with the overall grade determined in this step (see Appendix D of Technical Report Volume 2 [see the "Availability of Companion Documents" field]).

Practice Points

Where evidence-based recommendations were graded D because of a weak body of evidence, recommendations can be applied only with caution in practice. Furthermore, where no evidence was identified, evidence-based recommendations could not be developed. In these circumstances, practice points were developed by the CRG through a consensus-based process. These practice points are intended to guide clinical practice in the absence of evidence-based recommendations. Practice points were also developed where the CRG developed recommendations (graded C and above) but considered that additional information was required to guide clinical practice. Practice points were developed through a consensus-based process, which is outlined in Appendix 4 of Technical Report Volume 1 (see the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Grade of Recommendation

Grade A: Body of evidence can be trusted to guide practice.

Grade B: Body of evidence can be trusted to guide practice in most situations.

Grade C: Body of evidence provides some support for recommendation(s) but care should be taken in its application.

Grade D: Body of evidence is weak and recommendations must be applied with caution.

Practice Point: The systematic review found insufficient high-quality data to produce evidence-based recommendations, but the Clinical/Consumer Reference Group (CRG) felt that clinicians require guidance to ensure good clinical practice.

Cost Analysis

The literature search identified no published cost-effectiveness analysis on the use of massive transfusion protocols relevant to research question.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Public Consultation

Public consultation was conducted from Monday 12 April to Friday 14 May 2010, during which time the draft module was available on the National Blood Authority (NBA) Web site. Notification was posted in *The Australian* national newspaper, and the NBA invited a range of stakeholders, committees, working groups and interested people to provide submissions.

Twenty-seven formal submissions were received, including one very detailed submission from an independent international reviewer from Canada. The Clinical/Consumer Reference Group (CRG) met on 19 and 20 May 2010 to consider all responses to the public consultation submission and, where necessary, revise this module in accordance with the submissions.

Finalising the Module

The final draft of the Module and technical reports were reviewed by a guidelines development expert (formerly a Guidelines Assessment Registrar [GAR]) to assess compliance with National Health and Medical Research Council (NHMRC) requirements for externally developed guidelines. The Module was then reviewed by an Appraisal of Guidelines for Research and Evaluation (AGREE) II expert to assess the Module against international quality standards. The Module and accompanying documents were then sent to the NHMRC for methodological and independent peer review on 6 August 2010.

The module was further refined in response to the reviewer's recommendations.

Approval from the NHMRC was received on 12 November 2010.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Boffard KD, Riou B, Warren B, Choong PI, Rizoli S, Rossaint R, Axelsen M, Kluger Y, NovoSeven Trauma Study Group. Recombinant factor VIIa as adjunctive therapy for bleeding control in severely injured trauma patients: two parallel randomized, placebo-controlled, double-blind clinical trials. J Trauma. 2005 Jul;59(1):8-15; discussion 15-8. PubMed

Cotton BA, Au BK, Nunez TC, Gunter OL, Robertson AM, Young PP. Predefined massive transfusion protocols are associated with a reduction in organ failure and postinjury complications. J Trauma. 2009 Jan;66(1):41-8; discussion 48-9. PubMed

Dente CJ, Shaz BH, Nicholas JM, Harris RS, Wyrzykowski AD, Patel S, Shah A, Vercruysse GA, Feliciano DV, Rozycki GS, Salomone JP, Ingram WL. Improvements in early mortality and coagulopathy are sustained better in patients with blunt trauma after institution of a massive transfusion protocol in a civilian level I trauma center. J Trauma. 2009 Jun;66(6):1616-24. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Improvement of clinical outcomes by avoiding unnecessary exposure to blood components including:

- Optimisation of blood volume and red cell mass
- Minimisation of blood loss
- Optimisation of the patient's tolerance of anaemia

Potential Harms

Traditionally, it has been assumed that blood transfusion benefits patients; however, a benefit has not been demonstrable in many clinical scenarios. In addition, evidence is accumulating that transfusion-related acute lung injury is more common than previously thought, and that more recently identified conditions – including transfusion-related immunomodulation – may cause patients harm.

The risk of transmission of infectious diseases has reduced significantly in recent years through improved manufacturing and laboratory processes. Nevertheless, there is still a small potential for transfusion of an unrecognised infectious agent.

Despite improvements in systems management, there remains a risk of transfusion-related harm due to administrative error. Such an error has the potential to result in acute haemolytic reaction from ABO incompatibility, which may be fatal.

Of the recognised adverse events associated with transfusion, the most common is transfusion-associated circulatory overload, which is reported in up to 1% of patients receiving transfusions.

The clinical decision to undertake transfusion therapy should only be made after full consideration of the risks and benefits. Table B.1 in the original guideline document summarises the risks and benefits; Table B.2 puts the risks into perspective; and Table B.3 presents the Calman chart (United Kingdom risk per one year), which may be useful to clinicians for explaining risks to patients.

Contraindications

Contraindications

Permissive hypotension is contraindicated in patients with traumatic brain injury, because reduced perfusion pressure and oxygenation can lead to secondary brain injury.

Qualifying Statements

Qualifying Statements

- This document is a general guide to appropriate practice, to be followed subject to the circumstances, clinician's judgement and patient's preferences in each individual case. It is designed to provide information to assist decision making. Recommendations contained herein are based on the best available evidence published up to the dates shown in Appendix D in the original guideline document. The relevance and appropriateness of the information and recommendations in this document depend on the individual circumstances. Moreover, the recommendations and guidelines are subject to change over time.
- Each of the parties involved in developing this document expressly disclaims and accepts no responsibility for any undesirable consequences

arising from relying on the information or recommendations contained herein.
- This publication reflects the views of the authors and not necessarily the views of the Australian Government.
- Transfusion decisions for patients should take into account each individual's clinical circumstances and physiological status, and their treatment preferences and choices.
- If blood components are likely to be indicated, transfusion should not be a default decision. Instead, the decision on whether to transfuse should be carefully considered, taking into account the full range of available therapies, and balancing the evidence for efficacy and improved clinical outcome against the potential risks.

Implementation of the Guideline

Description of Implementation Strategy

Implementing, Evaluating and Maintaining the Guidelines

The National Blood Authority (NBA), in collaboration with the Steering Committee and Expert Working Group (EWG) members, developed a plan to guide appropriate communication on the implementation of this module. The plan identifies target audiences for the module, strategies and tools for effective implementation, communication channels and key messages.

Continued re-evaluation of the guidelines is necessary to reduce variation in practice patterns, support appropriate use of blood component therapy and reduce inappropriate exposure of patients to blood components. A plan was designed to evaluate implementation of the six modules of the guidelines and to determine:

- The extent to which the guidelines influence changes in clinical practice and health outcomes
- What factors (if any) contribute to noncompliance with the guidelines

The results of the evaluation will be used to inform future review of the guidelines. Economic issues were considered when formulating the evidence-based recommendations, and the recommendations appear unlikely to have major cost implications. Thus, cost will not be a barrier to implementation of the recommendations.

Implementation of Guideline Recommendations

The National Health and Medical Research Council (NHMRC) framework directs that guideline implementation should be considered at the same time as recommendations are formulated. The NHMRC evidence statement form contains questions related to the implementation of each guideline (see Appendix 3 in Technical Report Volume 1 [see the "Availability of Companion Documents" field]).

- Will this recommendation result in changes in usual care?
- Are there any resource implications associated with implementing this recommendation?
- Will the implementation of this recommendation require changes in the way care is currently organised?
- Are the guideline development group aware of any barriers to the implementation of this recommendation?

This section of the NHMRC evidence statement form was completed in consultation with the Clinical/Consumer Reference Group (CRG) when each recommendation was formulated and graded. Implementation issues are recorded in the NHMRC evidence statement forms presented in Appendix D of Technical Report Volume 2 (see the "Availability of Companion Documents" field).

Implementation Tools

Audit Criteria/Indicators

Clinical Algorithm

Mobile Device Resources

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Safety

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

National Blood Authority. Patient blood management guidelines: module 1 - critical bleeding/massive transfusion. Canberra ACT (Australia): National Blood Authority; 2011. 104 p. [100 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011

Guideline Developer(s)

National Blood Authority - National Government Agency [Non-U.S.]

Source(s) of Funding

Funding, Secretariat and Project Management was provided by the National Blood Authority Australia. The development of the final recommendations has not been influenced by the views or interests of the funding body.

Guideline Committee

Steering Committee

Expert Working Group

Clinical/Consumer Reference Group (CRG) - Critical Bleeding/Massive Transfusion

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

All members of the Steering Committee, Clinical/Consumer Reference Group (CRG) and Expert Working Group (EWG) declared any conflicts of interest before starting work on the guidelines. Conflicts of interest were reviewed at intervals during the development of the guidelines and required to be declared at the commencement of each meeting.

Guideline Endorser(s)

Australasian College for Emergency Medicine - Medical Specialty Society

Australasian Society for Emergency Medicine - Medical Specialty Society

Australian & New Zealand Intensive Care Society - Nonprofit Organization

Australian and New Zealand College of Anaesthetists - Medical Specialty Society

Australian Red Cross Blood Service - Nonprofit Organization

College of Intensive Care Medicine of Australia and New Zealand - Medical Specialty Society

Medical Oncology Group of Australia - Professional Association

Perinatal Society of Australia and New Zealand - Medical Specialty Society

Royal Australasian College of Surgeons - Professional Association

Royal Australian and New Zealand College of Obstetricians and Gynaecologists - Professional Association

Royal College of Nursing, Australia - Professional Association

Royal College of Pathologists of Australasia - Professional Association

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the National Blood Authority (NBA) Web site .

Availability of Companion Documents

The following are available:

- Patient blood management guidelines: module 1 - critical bleeding/massive transfusion. Quick reference guide. Canberra ACT (Australia): National Blood Authority; 2011. 15 p. Available from the National Blood Authority (NBA) Web site .
- Patient blood management guidelines: module 1 - critical bleeding/massive transfusion. Technical report. Volume 1. Review of the evidence and evidence-based recommendations for clinical practice. Canberra ACT (Australia): National Blood Authority; 2011. 111 p. Available from the NBA Web site .
- Patient blood management guidelines: module 1 - critical bleeding/massive transfusion. Technical report. Volume 2. Appendixes. Canberra ACT (Australia): National Blood Authority; 2011. 244 p. Available from the NBA Web site .

A variety of additional implementation resources, including audit tools, templates, case studies, and other guidance, are available from the NBA Web site . Instructions on how to add the guidelines to your mobile device are available from the NBA Web site .

Patient Resources

Various tools and resources to support patients in patient blood management decision making are available on the National Blood Authority (NBA) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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